REMARKS

In the present Office Action, the Examiner maintained the previous rejections of the pending claims as lacking written description, enablement and being indefinite. Each rejection raised by the Examiner is addressed separately below. In view of the claim amendments noted above and the remarks discussed below, Applicants respectfully request reconsideration of the merits of this patent application.

STATUS OF THE CLAIMS

Claims 10, 42-44, 47-49, 69 and 70 are pending. Claims 1-9, 11-41 and 45-46 have been cancelled, although Applicants retain the right to pursue the subject matter of any cancelled claims in any later-filed divisional applications. Claims 10, 42, 43 and 47-49 have been amended, and support for the amendments may be found in the application as filed. Claims 69-70 are new, and clarify subject matter of previously amended claims. Support for the new claims may be found in the application as filed. No new matter has been added.

REJECTIONS UNDER 35 U.S.C. § 112-WRITTEN DESCRIPTION

The rejection of claims 10, 14, 42-49 and 68 as failing to comply with the written description requirement has been maintained. The Examiner indicates that the specification does not provide written description for fragments of mouse, rat and human synaptotagmin II. The Examiner notes that the instant specification "merely states how the skilled artisan may "find" these polypeptides" and there is no indication that Applicants "were in possession of these polypeptides at the time of filing."

Applicants disagree with Examiner's characterization of the claims, but, solely to move prosecution forward, Applicants have deleted the language "(iii) the fragment of a mouse or rat synaptotagmin II homolog that corresponds to (i) or (ii)" i.e., the amino acids 40-60 of SEQ ID NO:7 or SEQ ID NO:9. Therefore, Applicants respectfully submit this rejection has been overcome, and withdrawal is requested.

REJECTIONS UNDER 35 U.S.C. § 112-ENABLEMENT

The rejection of claims 10, 14, 42-49 and 68 as lacking enablement has been maintained. Examiner alleges that Applicant is broadly claiming fragments of mouse or rat synaptotagmin II homologs that correspond to amino acids 40-60 of SEQ ID NOS: 7 and 9, and that the specification does not provide enablement for the "genus of all polypeptides as claimed."

Applicants disagree with Examiner's characterization of the claims, but, solely to move prosecution forward, Applicants have deleted the language "(iii) the fragment of a mouse or rat synaptotagmin II homolog that corresponds to (i) or (ii)" i.e., the amino acids 40-60 of SEQ ID NO:7 or SEQ ID NO:9. Therefore, Applicants respectfully submit this rejection has been overcome, and withdrawal is requested.

REJECTIONS UNDER 35 U.S.C. § 112-INDEFINITENESS

The rejection of claim 10 is rejected for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the claimed invention has also been maintained. The Examiner alleges that claim 10 is unclear because it states that the ligand is selected from BoNT/B and an antibody at one place but also states that the ligand is not a botulinum toxin at another place. Applicants respectfully submit that this amendment has been overcome by the appropriate amendment to the claims.

Specifically, claim 10 has been amended to recite:

> 10. A complex of a ligand and a polypeptide, wherein the polypeptide comprises the isolated amino acid sequence selected from (i) the amino acids 40-60 of SEQ ID NO:7 (mouse synaptotagmin II botulinum toxin serotype B (BoNT/B)-binding domain) and (ii) the amino acids 40-60 of SEQ ID NO:9 (rat synaptotagmin II botulinum toxin serotype B (BoNT/B)-binding domain), wherein the ligand is BoNT/B, and wherein the ligand binds to the polypeptide at amino acids 40 to 60 of SEQ ID NO:7 or SEQ ID NO:9.

Specifically, claim 10 has been amended to clarify that the polypeptide comprises the "isolated" amino acid sequence and that the ligand is BoNT/B. By "isolated" Applicants mean to exclude a full-length syt II polypeptide. Support for this may be found in the application as filed at paragraph [0027] of the published application. There, an isolated nucleic acid is defined, in

part, as having "a structure that is not identical to that of any naturally occurring genomic nucleic acid." This would exclude a full length syt II. The application as filed clearly states that a polypeptide that contains the full length syt II is "specifically excluded" from the invention (emphasis added, paragraph [0028] of the published application). Accordingly, Applicants submit as presently amended, claim 10 clearly recites a complex of a polypeptide comprising an isolated (i.e., not full length) amino acid sequence and BoNT/B (i.e., the ligand) bound together at amino acids 40 to 60 of SEQ ID NO:7 or SEQ ID NO:9. Support for this amendment may also be found in the application as filed at paragraphs [0010] and [0042] of the published application.

New claim 69 mimics this, albeit the ligand is an antibiotic. New claim 69 recites:

> 69. A complex of a ligand and a polypeptide, wherein the polypeptide comprises the amino acid sequence selected from (i) the amino acids 40-60 of SEQ ID NO:7 (mouse synaptotagmin II botulinum toxin serotype B (BoNT/B)-binding domain) and (ii) the amino acids 40-60 of SEQ ID NO:9 (rat synaptotagmin II botulinum toxin serotype B (BoNT/B)-binding domain), wherein the ligand is an antibody against said amino acid sequence, and binds to the polypeptide at amino acids 40 to 60 of SEQ ID NO:7 or SEQ ID NO:9, thereby reducing binding of BoNT/B to the polypeptide.

Specifically, new claim 69 clarifies that the polypeptide binds the antibody at amino acids 40-60 of SEQ ID NOS: 7 or 9. Support for this can be found in the application as filed at paragraphs [0010], [0027], [0028], [0041] and [0042]. New claim 70 depends from claim 69, and clarifies that the polypeptide further comprises a binding site for a ganglioside. Support for new claim 70 may be found in the application as filed at paragraph [0022].

Accordingly, as presently amended, Applicants submit that claim 10, and new claims 69-70 overcome the present indefiniteness rejection. Withdrawal of this rejection is requested.

SUMMARY AND FEES

In the present response Applicants have amended claims 10, 42, 43 and 47-49, and added new claims 69 and 70. No new matter has been added. The application is now believed to be in condition for allowance and allowance of the same is requested. If all the claims are not allowed, Applicant requests a telephone interview with the Examiner and his supervisor. The Commissioner is authorized to charge any fees under 37 CFR § 1.17 that may be due on this application to Deposit Account 17-0055. Applicants have enclosed a Petition for Three-Months Extension of Time and a Request for Continued Examination. No further fees are believed due. However, if further fees are necessary, please charge Deposit Account 17-0055. The Commissioner is also authorized to treat this amendment and any future reply in this matter requiring a petition for an extension of time as incorporating a petition for extension of time for the appropriate length of time as provided by 37 CFR § 136(a)(3).

Respectfully submitted,

Date : August 17, 2009

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